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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,278	01/22/2004	Robert A. Donahue JR.	0942.4710003	3164
26111	7590	05/09/2006		EXAMINER
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			NASHED, NASHAATT	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,278	DONAHUE ET AL.	
	Examiner Nashaat T. Nashed, Ph. D.	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: ____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>5/17/04</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: ____.

The application has been amended as requested in the communication filed January 22, 2004. Accordingly, Claims 2-30 have been canceled.

Claim 1 is pending.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 1 is rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter.

In the absence of the hand of man, naturally occurring microorganisms are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "A biologically pure culture". The claim is drawn to a bacterium including *Escherichia coli* containing F' genetic material. The F' genetic material is a natural bacterial genes, and therefore, the claims are drawn to naturally occurring bacterium. It should be noted that the enhanced transformation efficiency is an intrinsic property of a bacterium containing the F' genetic material.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,274,369 (369). Although the conflicting claims are not identical, they are not patentably distinct

from each other because the claims of the instant application are drawn to a bacterium containing the F' genetic material including *E. coli*, method of making the bacterium and producing the bacterium. Claims 1-14 of the '369 patent are drawn to an *E. coli* containing the F' genetic material with increases transformation efficiency, and process of making. The claim of the instant application is directed to any bacterium comprising the F' genetic material and capable of an enhanced transformation efficiency.

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,709,854 ('854). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a bacterium containing the F' genetic material including *E. coli*, method of making the bacterium and producing the bacterium. Claims 1-17 of the '854 patent are drawn to an *E. coli* containing the F' genetic material with increases transformation efficiency and composition thereof. The claim of the instant application is directed to any bacterium comprising the F' genetic material and capable of an enhanced transformation efficiency.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to all possible bacterium containing F' genetic material, process of making said bacterium, and a preparation of said bacterium. The specification, however, only provides a single representative species, i. e., *Escherichia coli* encompassed by these claims. There is no disclosed structure for the F' genetic material and there is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe any additional representative species of these bacterium containing the F' genetic material by any identifying structural characteristics or properties other than the enhanced transformation efficiency recited in the claim, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to *E. coli* containing the F' genetic material prepared by mating of two strains of the bacteria. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these claims. The claims are broader than the enablement provided by the disclosure with regard to the huge number of all possible bacterium which may contain the F' genetic material. Factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses any bacterium containing the F' genetic material. The specification fails to teach any nucleic acid from any source, which has the F' genetic material activity, any bacterium other than *E. coli* containing the F' genetic materials, or the effects of the F' episome on other bacteria with regard to their ability to transform. Also, the specification does not teach the construction of F' plasmid or the incorporation of the F' episome into a bacterium gene by recombinant methods. The specification provides guidance and examples in the form of an assay to prepare the *E. coli* DH5 α containing the F' genetic material by breeding two strain of *E. coli* (examples 1 and 2) and transforming the resulting strain (example 3). While molecular and biological techniques to manipulate and transform cells known in the prior art and the skill of the artisan are well developed, knowledge regarding the effects of the F' genetic materials on other bacteria and their efficiency to be transformed, and the nucleic acid sequence of the F' genetic material are lacking. Thus, searching for a DNA fragment containing the F' genetic material, constructing a plasmid containing the said DNA fragment and examining the effect of the F' genetic material on vast number of bacterial species is well outside the realm of routine experimentation and predictability in the art of success in obtaining a bacterium containing the F' genetic material and has enhanced efficiency of being transformed is extremely low. The amount of experimentation to screen for a DNA encoding the F' genetic material and testing the effect of the gene on various bacteria is enormous. Since routine experimentation in the art does not include screening vast numbers of genes and strains of bacteria where the expectation of obtaining the desired bacterium is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the effects of the F' genetic material on various bacteria, how such a genetic material would affect the ability of the bacterium to be transformed, how to construct a plasmid containing the F' genetic material, and the structure of the F' genetic material. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Greener (U.S. Patent 5,512,468 ('468)).

The '468 patent teaches an *E. coli* bacteria containing the F', which has an enhanced transformation capability, see example 1, in particular, the paragraph bridging columns 8 and 9. The teaching of the '468 patent meet all the limitation found in claim 1.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by Liss, L. R. (IDS, Reference No. AR17) or GIBCO-BRL catalog, 1993 (IDS, Reference No. AT12).

Liss, L. R. teach the use of *E. coli* called DH5 α F' as a host for the M13 sequencing vector. Both *E. coli* DH5 α F' and DH5 α F'IQ are commercially available from GIBCO-BRL since 1993, contain a stable F' episome, and have high transformation efficiency (claim 1), see the enclosed relevant portion of GIBCO-BRL catalog.

Claims 1 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bullock *et al.* (IDS, reference No. AR13).

Bullock *et al.* disclose a method of making a high efficiency transforming strain of *E. coli* XL1-blue which contains the F' episome by breeding strains of *E. coli*, see page 337 (1-4, 7, 8, 14, 16-18, 21-23 and 26-28), right column, paragraph 3.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1656